

used for both the first and second analyte area 14 and 16 purely for these test purposes. The specific antibody was anti-mouse IgG. The enzyme label was alkaline phosphatase (alp). The enzyme substrate was para amino phenyl phosphate (PAPP) and the enzymatic reaction product was para amino phenol (PAP).

DISCUSSION

Applicant has canceled claim 10 which was rejected under 35 U.S.C. §112. The other issue is the rejection of 35 U.S.C. §102 based on the Meyerhoff '203 reference. It is the Examiner's position that the Meyerhoff substantially discloses the claimed invention and does not require use of stirers and therefore it is an anticipation of the present claim. It is Applicant's position that if the Meyerhoff device is used with multiple analytes, it requires a stirrer or it would be inoperative.

The purpose of the invention disclosed in Meyerhoff '203 is to take a sample such as whole blood, filter it and measure one or more analytes. The larger particles are filtered from the blood allowing the analyte to pass through the filter and be measured. They have combined the electrode function with the filtration function.

Figure 11 shows a structure wherein multiple analytes are detected and this is further elaborated in Fig. 12 and Fig. 15. The operation of the device in the Meyerhoff reference is set forth in column 15. It recites that a steady state current is achieved within 50 seconds for all assays. As shown in Fig. 7A to Fig. 7D, response times appear to be in the range of 30 seconds to a minute according to the material tested. If produced enzymatic product is allowed to freely migrate about the surface of the electrode without any way to prevent it from migrating from one electrode to the next, the enzymatic product

from one electrode will significantly effect the reading in the adjacent electrode. Thus, as shown in Meyerhoff, there is a stirrer with a large volume of liquid on either side of the electrode. This is shown in the only drawings that show physical devices i.e., Figs. 2A and 12. Thus, without active mixing, the apparatus disclosed in the Meyerhoff reference would clearly not function when testing for multiple analytes.

Further, with respect to claim 10, Applicant would maintain that this is clearly different from the invention disclosed in the Meyerhoff '203 reference. That reference at column 10, first full paragraph, states: "No useful analytical results are obtained when substrate is added directly to the same sample size of the membrane for samples at a number of different pH's (7.4, 9.0 and 10.0). In such cases, the amperometric signal continues to increase until all of the substrate and bulk solution is consumed by the high concentration of ALP-AB on the sample side of the membrane. Consequently no correlation between the amperometric signals and varying levels of HCG can be obtained."

Thus, claim 10 of the present application is clearly distinguishable over the Meyerhoff reference which requires a liquid pervious electrode support.

Applicant has amended the specification to provide the antecedent basis for the specific claim language contained in claim 10. As Applicant has previously discussed, this is not new material in that polystyrene sheets are liquid impervious and further the drawings clearly demonstrate that we are dealing with a liquid impervious material.

In light of this, Applicant would request reconsideration of the rejection of the outstanding office action and allowance of the pending claims.

Respectfully submitted,

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VERSIONS WITH MARKINGS TO SHOW CHANGES MADE

In the Specification please rewrite the first sentence to read as follows:

"Applicant claims priority to Application Serial No. 60/078,162 filed March 16, 1998 now abandoned.

Amend the specification at page 10, line 3, to read:

electrodes. Four electrodes were inserted through small holes in the side wall 40 of the cell. Antibody 18 and 20 was immobilized on a piece of polystyrene sheet 12 which forms the bottom of the cell 10. The electrodes rest on the polystyrene sheet 12 which is liquid impervious leaving no gap in between. The distance between two adjacent electrodes 22 and 24 was 2.5mm. Both the assay and electrochemical detection were carried out in the cell which had a volume of 150 micro liters. As discussed below, the same antibody was used for both the first and second analyte area 14 and 16 purely for these test purposes. The specific antibody was anti-mouse IgG. The enzyme label was alkaline phosphatase (alp). The enzyme substrate was para amino phenyl phosphate (PAPP) and the enzymatic reaction product was para amino phenol (PAP).